IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Zoltan Kiss	**Examiner:**	
Appln. No.:	10/582,391	**Group Art Unit:**	
Filing Date:	June 9, 2006	**Confirmation No.:**	
Title:	METHOD FOR IMPROVING INSULIN SENSITIVITY BY ADMINISTERING AN INHIBITOR OF ANTITRYPSIN	**Customer No.:**	25764
		Docket No.:	59496 - 336756

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

I CERTIFY THAT THIS CORRESPONDENCE IS BEING ELECTRONICALLY TRANSMITTED TO THE U.S. PATENT AND TRADEMARK OFFICE ON DECEMBER 27, 2006.

Amber Friendt

INFORMATION DISCLOSURE STATEMENT

In compliance with the duty imposed by 37 C.F.R. 1.56, and in accordance with C.F.R. sections 1.97 *et seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Consideration of each of the documents listed on the attached SB/08 form(s) is respectfully requested. The filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is construed to be, prior art or material to the patentability of the present application.

This Information Disclosure Statement is being filed before the receipt of an Office Action on the merits. No fee is believed to be necessary. However, should any fee be required, the Commissioner is authorized to charge our Deposit Account No. 06-0029 and is requested to notify us of the same.

Respectfully submitted,

FAEGRE & BENSON LLP

By: _____
Tanya S. D'Souza, Reg. No. 56,948
612/766-7835 Customer No.: 25764

Dated: December 27, 2006

fb.us.1726342.01

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	10/582,391
Filing Date	December 9, 2004
First Named Inventor	Zoltan Kiss
Art Unit	1618
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	59496 - 336756

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/S.G./		US- 5,593,971	01-14-1997	Tschollar et al.	
		US- 6,133,293	10-17-2000	Ikeda et al.	
		US- 6,174,859 B1	01-16-2001	Lezdey et al.	
		US- 6,515,117 B2	02-04-2003	Ellsworth et al.	
		US- 6,555,519 B2	04-29-2003	Washburn	
		US- 6,608,112 B1	08-19-2003	D'Armiento et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] - Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Shirley Gembeh/	Date Considered	08/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	4

Complete if Known	
Application Number	10/582,391
Filing Date	July 14, 2006
First Named Inventor	Zoltan Kiss
Art Unit	1618
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	59496 - 336756

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
/S.G./		ZIMMET et al., "Global and societal implications of the diabetes epidemic," *Nature* **414**, pp. 782-787, 2001	
		SALTIEL et al., "Insulin signaling and the regulation of glucose and lipid metabolism," *Nature* **414**, pp. 799-806, 2001	
		BELL et al., "Diabetes mellitus and genetically programmed defects in β-cell function." *Nature* **414**, pp. 788-791 2001	
		MATHIS et al., "β-cell death during progression to diabetes." *Nature* **414**, pp. 792-798, 2001	
		SALTIEL, "New perspectives into the molecular pathogenesis and treatment of Type 2 diabetes," *Cell* **104**, pp. 517-529, 2001	
		MOLLER, "New drug targets for Type 2 diabetes and the metabolic syndrome," *Nature* **414**, pp. 821-827, 2001	
		BROWNLEE, "Biochemistry and molecular cell biology of diabetic complications," *Nature* **414**, pp. 813-820, 2001	
		HO et al., "Antioxidants, NFκB activation, and diabetogenesis," *Proc. Soc. Exp. Biol. Med.* **222**, pp. 205-213, 1999	
		BODEN et al., "FFA cause hepatic insulin resistance by inhibiting suppression of glycogenolysis," Am. J. Physiol. Endocrinol. Metab. **283**, pp. E-12-E19, 2001	
		YU et al., "Mechanism by which fatty acids inhibit insulin activation of insulin receptor substrate-1 (IRS-1)-associated phosphatidylinositol 3-kinase in Muscle," *J. Biol. Chem.* **277**, pp. 50230-50236, 2002	
		MAEDLER et al., "Distinct effects of saturated and monounsaturated fatty acids on β-cell turnover and function," *Diabetes* **50**, pp. 69-76, 2001	
		PRADHAN et al., "C-reactive protein, interleukin 6, and risk of developing Type 2 diabetes mellitus," *JAMA*, **286**, pp. 327-334, 2001	
		THOMPSON et al., "Insulin modulation of acute-phase protein production in a human hepatoma cell line," *Cytokine* **3**, pp. 619-626, 1991	
		CAMPOS et al., "Insulin is a prominent modulator of the cytokine-stimulated expression of acute-phase plasma protein genes," *Mol. Cell. Biol.* **12**, 1789-1797, 1992	
		GANROT et al., "Serum concentration of α_2-macroglobulin, haptoglobin and α_1-antitrypsin in diabetes mellitus," *Acta Endocrinologica* **55**, pp. 537-544, 1967	

Examiner Signature	/Shirley Gembeh/	Date Considered	08/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	10/582,391
Filing Date	July 14, 2006
First Named Inventor	Zoltan Kiss
Art Unit	16181618
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	59496 - 336756

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
/S.G./		MCMILLAN, "Increased levels of acute-phase serum proteins in diabetes," *Metabolism* **38**, pp. 1042-1046, 1989	
		SCHMIDT et al., "Markers of inflammation and prediction of diabetes mellitus in adults," *The Lancet* **353**, pp. 1649-1652, 1999	
		JANCIAUSKIENE, "Conformational properties of serine proteinase inhibitors (serpins) confer multiple pathophysiological roles," *Biochim. Biophys. Acta* **1535**, pp. 221-235, 2001	
		WEWERS et al., "Replacement therapy for alpha$_1$-antitrypsin deficiency associated with emphysema," *N. Engl. J. Med.* **316**, pp. 1055-1062, 1987	
		PERRAUD et al., "Proliferation of rat astrocytes, but not of oligodendrocytes, is stimulated in vitro by protease inhibitors," *Int. J. Devl. Neuroscience* **6**, pp. 261-266, 1988	
		SHE et al., "α_1-antitrypsin can increase insulin-induced mitogenesis in various fibroblast and epithelial cell lines," *FEBS Lett.* **473**, pp. 33-36, 2000	
		DABBAGH et al., "Alpha-1-antitrypsin stimulates fibroblast proliferation and procollagen production and activates classical MAP kinase signaling pathways," *J. Cell. Physiol.* **186**, pp. 73-81, 2001	
		GRAZIADEI et al., "The acute phase protein α_1-antitrypsin inhibits growth and proliferation of human early erythroid progenitor cells (burst-forming units-erythroid) and of human erythroleukemic cells (K562) in vitro by interfering with transferring iron uptake," *Blood* **83**, pp. 260-268, 1994	
		YAVELOW et al., "α_1-antitrypsin blocks the release of transforming growth factor-α from MCF-7 human breast cancer cells," *J. Clin. Endocrinol. Metab.* **82**, pp. 745-752, 1997	
		OZEKI et al., "α_1-antitrypsin and hepatic fibrosis," *Br. J. Exp. Path.* **70**, pp. 143-152, 1989	
		GRAZIADEI, "Modulation of iron metabolism in monocytic THP-1 cells and cultured human monocytes by the acute-phase protein α_1-antitrypsin," *Exp. Hematol.* **26**, pp. 1053-1060, 1998	
		JANCIAUSKIENE et al., "An interaction between Gemfibrozil and alpha$_1$-antitrypsin," *J. Internal Med.* **236**, pp. 357-360, 1994	
		JANCIAUSKENE et al., "The interaction of hydrophobic bile acids with the α_1-proteinase inhibitor," *FEBS Lett.* **343**, pp. 141-145, 1994	
		JANCIAUSKIENE et al., "In vitro complex formation between cholesterol and α_1-proteinase inhibitor," *FEBS Lett.* **316**, pp. 269-272, 1993	

Examiner Signature	/Shirley Gembeh/	Date Considered	08/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known	
Application Number	10/582,391
Filing Date	July 14, 2006
First Named Inventor	Zoltan Kiss
Art Unit	1618
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	59496 - 336756

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
/S.G./		YUAN et al., "Changes in composition and distribution of LDL subspecies in hypertriglyceridemic and hypercholesterolemic patients during gemfibrozil therapy," *Atherosclerosis* **110**, pp. 1-11, 1994	
/S.G./		SCHAEFER et al., "Effects of regular and extended-release gemfibrozil on plasma lipoproteins and apolipoproteins in hypercholesterolemic patients with decreased HDL cholesterol levels," *Atherosclerosis* **127**, pp. 113-122, 1996	
/S.G./		RUBINS et al., "Gemfibrozil for the secondary prevention of coronary heart disease in men with low levels of high-density lipoprotein cholesterol," *N. Engl. J. Med.* **341**, pp. 410-418, 1999	
/S.G./		SCHULZE et al., "Evidence for the extent of insertion of the active site loop of intact α_1 proteinase inhibitor in β-Sheet A," *Biochemistry* **31**, pp. 7560-7565, 1992	

Examiner Signature	/Shirley Gembeh/	Date Considered	08/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.
SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**